participated in the treatment of the patient, the patient is a relative, or the practitioners have a financial interest in the health care facility as described in § 466.98(d).

(c) *Peer involvement in quality review studies.* Practitioners must be involved in the design of quality review studies, development of criteria, and actual conduct of studies involving their peers.

(d) *Consultation with practitioners other than physicians.* To the extent practicable, a PRO must consult with nurses and other professional health care practitioners (other than physicians defined in 1861(r) (1) and (2) of the Act) and with representatives of institutional and noninstitutional providers and suppliers with respect to the PRO's responsibility for review.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985]

§ 466.104 Coordination of activities.

In order to achieve efficient and economical review, a PRO must coordinate its activities (including information exchanges) with the activities of—

(a) Medicare fiscal intermediaries and carriers;

(b) Other PROs; and

(c) Other public or private review organizations as may be appropriate.

PART 473—RECONSIDERATIONS AND APPEALS

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

Sec.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

SOURCE: 50 FR 15372, Apr. 17, 1985, unless otherwise noted.

§ 473.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Peer Review Organization (PRO) or its subcontractor of initial denial determinations concerning services furnished or proposed to be furnished under Medicare;

(b) Hearings and judicial review of reconsidered determinations; and

(c) PRO review of a change in diagnostic and procedural coding information.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.12 Statutory basis.

(a) Under section 1154 of the Act, a PRO may make an initial determination that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting.

(b) Under section 1155 of the Act, the following rules apply:

(1) A Medicare beneficiary, a provider, or an attending practitioner who is dissatisfied with an initial denial determination under paragraph (a) of this section is entitled to a reconsideration by the PRO that made that determination.

(2) The beneficiary is also entitled to the following:

(i) A hearing by an administrative law judge if $200 or more is still in controversy after a reconsidered determination.

(ii) Judicial review if $2000 or more is still in controversy after a final determination by the Department.

(c) Under section 1866(a)(1)(F) of the Act, a hospital that is reimbursed by the Medicare program must maintain an agreement with a PRO under which the PRO reviews the validity of diagnostic information furnished by the hospital.

[50 FR 15372, Apr. 17, 1985, as amended at 60 FR 50442, Sept. 29, 1995]

§473.14 Applicability.

(a) *Basic provision.* This subpart applies to reconsiderations and hearings of a PRO initial denial determination involving the following issues:

(1) Reasonableness of services.

(2) Medical necessity of services.

(3) Appropriateness of the inpatient setting in which services were furnished or are proposed to be furnished.

(b) *Concurrent appeal.* A reconsideration or hearing provided under this subpart fulfills the requirements of any other review, hearing, or appeal under the Act to which a party may be entitled with respect to the same issues.

(c) *Nonapplicability of rules to related determinations.* (1) A PRO may not reconsider its decision whether to grant grace days.

(2) Limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under section 1879 and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by an intermediary, carrier or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§473.15 PRO review of changes resulting from DRG validation.

(a) *General rules.* (1) A provider or practitioner dissatisfied with a change to the diagnostic or procedural coding information made by a PRO as a result of DRG validation under section 1866(a)(1)(F) of the Act is entitled to a review of that change if—

(i) The change caused an assignment of a different DRG; and

(ii) Resulted in a lower payment.

(2) A beneficiary may obtain a review of a PRO DRG coding change only if that change results in noncoverage of a furnished service.

(3) The individual who reviews changes in DRG procedural or diagnostic information must be a physician, and the individual who reviews changes in DRG coding must be qualified through training and experience with ICD–9–CM coding.

(b) *Procedures.* Procedures described in §§473.18 through 473.36, and 473.48 (a) and (c) for a PRO reconsideration or reopening also apply to PRO review of a DRG coding change.

(c) *Finality of review.* No additional review or appeal for matters governed by paragraph (a) of this section is available.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§473.16 Right to reconsideration.

A beneficiary, provider or practitioner who is dissatisfied with a PRO initial denial determination on one of the issues specified in §473.14(a) has a right to a reconsideration of that determination by the PRO that made the initial denial determination.

§473.18 Location for submitting requests for reconsideration.

(a) *Beneficiaries.* Except as provided in paragraph (c) of this section concerning requests for expedited reconsideration, a beneficiary who wishes to

obtain a reconsideration must submit a written request to one of the following:

(1) The PRO or the PRO subcontractor that made the initial determination.

(2) An SSA District Office.

(3) A Railroad Retirement Board Office, if the beneficiary is a railroad retiree.

(b) *Others.* A provider, physician or other practitioner that wishes to obtain reconsideration must submit a written request to the PRO or PRO subcontractor that made the initial determination.

(c) *Expedited reconsideration.* A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the PRO.

§ 473.20 Time limits for requesting reconsideration.

(a) *Basic rules.* (1) Except for a request for expedited reconsideration as provided in paragraph (c) of this section, or a late request with good cause under § 473.22, a dissatisfied party must file a request for reconsideration within 60 days after receipt of the notice of an initial determination.

(2) The date of receipt of the notice of the initial determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

(b) *Late filing of request.* A PRO will accept a request filed after 60 days after receipt of the notice of the initial determination if the PRO finds under the criteria set forth in § 473.22 that there was good cause for the party's failure to file a timely request.

(c) *Request for expedited reconsideration.* A request for an expedited reconsideration under § 473.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

§ 473.22 Good cause for late filing of a request for a reconsideration or hearing.

(a) *General Rule.* In determining whether a party has good cause for not filing a request for reconsideration or hearing timely, the PRO or ALJ, respectively, must consider the following:

(1) What circumstances kept the party from making the request on time.

(2) Whether an action by the PRO misled the party.

(3) Whether the party understood the requirements of the Act as affected by amendments to the Act, other legislation, or court decisions.

(b) *Examples.* Examples of circumstances in which good cause may exist include, but are not limited to, the following:

(1) A party was seriously ill and was prevented from requesting a reconsideration in person, through another person, or in writing.

(2) There was a death or serious illness in a party's immediate family.

(3) Important records were accidentally destoryed or damaged by fire or other cause.

(4) A party made a diligent effort but could not find or obtain necessary relevent information within the appropriate time period.

(5) A party requested additional information to further explain the determination within the time limit, and requested reconsideration within 60 days of receiving the explanation (or within 30 days for a Departmental Appeals Board hearing).

(6) The PRO gave the party incorrect or incomplete information about when and how to request a reconsideration or hearing.

(7) A party sent the request to another Government agency in good faith within the time limit, but the request did not reach an office authorized to receive the request until after the time period had expired.

(8) Other unusual or unavoidable circumstances exist that—

(i) Show that a party could not have known of the need to file timely; or

(ii) Prevented a party from filing timely.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996]

§ 473.24 Opportunity for a party to obtain and submit information.

(a) Subject to the rules concerning disclosure of PRO information in section 1160 of the Act, at the request of a

provider, practitioner or beneficiary, the PRO must provide an opportunity for examination of the material upon which the initial denial determination was based. The PRO may not furnish a provider, practitioner or beneficiary with—

(1) A record of the PRO deliberation; or

(2) The identity of the PRO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their consent.

(b) The PRO may require the requester to pay a reasonable fee for the reproduction of the material requested.

(c) The PRO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

§473.26 Delegation of the reconsideration function.

A PRO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a PRO subcontractor.

§473.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is—

(a) Qualified under §466.98 of this chapter to make an initial determination.

(b) Not the individual who made the initial denial determination.

(c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of PRO review.

§473.30 Evidence to be considered by the reconsideration reviewer.

A reconsidered determination must be based on—

(a) The information that led to the initial determination;

(b) New information found in the medical records; or

(c) Additional evidence submitted by a party.

§473.32 Time limits for issuance of the reconsidered determination.

(a) *Beneficiaries.* If a beneficiary files a timely request for reconsideration of an initial denial determination, the PRO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits—

(1) Within three working days after the PRO receives the request for reconsideration if—

(i) The beneficiary is still an inpatient in a hospital for the stay in question when the PRO receives the request for reconsideration; or

(ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.

(2) Within 10 working days after the PRO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the PRO receives the request for reconsideration.

(3) Within 30 working days after the PRO receives the request for reconsideration if—

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely.

(b) *Providers or practitioners.* If the provider or practitioner files a request for reconsideration of an initial determination, the PRO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§473.34 Notice of a reconsidered determination.

(a) *Notice to parties.* A written notice of a PRO reconsidered determination must contain the following;

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.

(3) A statement explaining the Medicare payment consequences of the reconsidered determination.

(4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.

(b) *Notice to payers.* (1) A PRO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.

(2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

§ 473.36 Record of reconsideration.

(a) *PRO requirements.* A PRO must maintain the record of its reconsideration until the later of the following:

(1) Four years after the date on the notice of the PRO's reconsidered determination.

(2) Completion of litigation and the passage of the time period for filing all appeals.

(b) *Contents of the record.* The record of the reconsideration must include:

(1) The initial determination.

(2) The basis for the initial determination.

(3) Documentation of the date of the receipt of the request for reconsideration.

(4) The detailed basis for the reconsidered determination.

(5) Evidence submitted by the parties.

(6) A copy of the notice of the reconsidered determination that was provided to the parties.

(7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.

(c) *Confidentiality.* The record of a PRO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 473.38 Finality of a reconsidered determination.

A PRO reconsidered determination is final and binding upon all parties to the reconsideration unless—

(a) A hearing is requested in accordance with § 473.40 and a final decision rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with § 473.48.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a PRO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.

(b) *Subject matter.* A beneficiary has a right to a hearing on the following issues:

(1) Reasonableness of the services.

(2) Medical necessity of the services.

(3) Appropriateness of the setting in which the services were furnished.

(c) *Governing provisions.* The provisions of subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in subpart G to initial and reconsidered determinations made by an intermediary, carrier, or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985]

§ 473.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 473.40 must submit a written request to one of the following:

(1) The office of the PRO or PRO subcontractor that made the initial determination.

(2) A SSA District Office.

(3) An office of the Office of Hearings and Appeals of SSA.

(4) An office of the Railroad Retirement Board, in the case of a beneficiary who is a railroad retiree.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 days of receipt of the notice of the PRO reconsidered determination, unless the time is extended for good cause as provided in §473.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

§473.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ determines the amount in controversy in accordance with §405.740(a) of this chapter for Part A services or §405.817(a) of this chapter for Part B services. When two or more appellants submit a request for hearing, the ALJ determines the amount in controversy in accordance with §405.740(b) of this chapter for Part A services and §405.817(b) of this chapter for Part B services.

(b) If the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, notifies the parties to the hearing that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least $200.

(c) At the end of the 15-day period, if the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties to the hearing and the PRO that the PRO reconsidered determination is conclusive for Medicare payment purposes.

[50 FR 15372, Apr. 17, 1985, as amended at 59 FR 12184, Mar. 16, 1994]

§473.46 Departmental Appeals Board and judicial review.

(a) The circumstances under which the Departmental Appeals Board will review an ALJ hearing decision or dismissal are specified in 20 CFR 404.970, Cases the Appeals Council will review.

(b) If $2,000 or more is in controversy, a party may obtain judicial review of an Departmental Appeals Board decision, or an ALJ hearing decision if a request for review by the Departmental Appeals Board was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Departmental Appeals Board decision or denial.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996; 61 FR 32349, June 24, 1996; 61 FR 42386, Aug. 15, 1996]

§473.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) *PRO reopenings*—(1) *General rule.* A PRO or PRO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in §473.15, that is otherwise final, may reopen and revise the reconsidered determination or review, either on its own motion or at the request of a party, within one year from the date of the reconsidered determination or review.

(2) *Extension of time limit.* A PRO or PRO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in §473.15, that is otherwise final, after one year but within four years of the date of the determination or review if—

(i) The PRO receives new material evidence;

(ii) The PRO erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or

(iv) There is a clerical error in the statement of the reconsidered determination.

(b) *ALJ and Departmental Appeals Board Reopening—Applicable procedures.* The ALJ or the Departmental Appeals

Board, whichever made the final decision, may reopen and revise the decision in accordance with the procedures set forth in §405.750(b) of this chapter, which concerns reopenings and revisions under subpart G of part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or the Departmental Appeals Board may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996]

PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

GENERAL PROVISIONS

Sec.

PRO ACCESS TO INFORMATION

PRO RESPONSIBILITIES

DISCLOSURE OF NONCONFIDENTIAL INFORMATION

DISCLOSURE OF CONFIDENTIAL INFORMATION

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—[Reserved]

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

SOURCE: 50 FR 15359, Apr. 17, 1985, unless otherwise noted.

GENERAL PROVISIONS

§476.101 Scope and definitions.

(a) *Scope.* This subpart sets forth the policies and procedures governing—

(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Peer Review Organization (PRO) (or the review component of a PRO subcontractor) in performance of its responsibilities under the Act and these regulations; and